

Certificate of Analysis
GM501 Hyaluronidase

Batchnumber	HYA-2330
Production date	13 November 2023
Expiry date	30 November 2024
Total volume (ml)	3800
Batchnumber HSA	B03H025323
Batchnumber HYA	S1047H40

Parameter	Results	Specifications
pH	7,55	7,30-7,60
Osmolality	279	270-290 mOsm/kg
Endotoxin	< 0,1	<0,5 EU/ml
Concentration HSA	3,8	3,2-4,8 g/l
Enzyme activity	69-102	40-160 IU/ml
Sterility test (according to the current Ph.Eur.2.6.1 /USP<71>)	No growth	No growth
Mouse Embryo Assay (1-cell)	100	≥ 80 %

Source materials from which this product was derived was found negative when tested for antibodies against HIV-1/2 and HCV and non-reactive for HbsAg, HBV RNA, HIV-1 RNA and syphilis. No known test method can offer assurance that products derived from human blood will not transmit infectious agents. Therefore, handle all specimens as if capable of transmitting HIV or hepatitis.

Release date	28 November 2023
Released by	Nicole Geiger
Signature	

REV 09_00 /2023-09-15